Complete Summary

GUIDELINE TITLE

The management of menorrhagia in secondary care.

BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists. The management of menorrhagia in secondary care. London: RCOG Press; 1999 Jul. 77 p. (Evidence-based clinical guidelines; no. 5). [276 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Menorrhagia

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel

Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations to aid gynecologists in the management of menorrhagia after referral to secondary care which will improve the quality of care provided for women with menorrhagia.

TARGET POPULATION

- Women of reproductive age with heavy menstrual bleeding that occurs over several consecutive cycles who have been referred to secondary care.

The guideline does not apply to women with any other abnormalities of the menstrual cycle, such as irregular bleeding.

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

1. Re-evaluation of menstrual history
2. Abdominal, bimanual and speculum examinations
3. Full blood count and serum ferritin measurement

   Note: Serum ferritin level is not recommended as a routine test in women complaining of menorrhagia.

4. Tests for thyroid function and bleeding disorders when features suggestive of menorrhagia are present in the history or on examination
5. Transvaginal ultrasound and/or hysteroscopy of the uterine cavity
6. Endometrial biopsy
7. Dilatation and curettage
8. Measurement of menstrual blood loss
   - Objective measurement: alkaline haematin method and modified alkaline haematin method
   - Semi-objective measurement: pictorial blood loss assessment chart
   - Other methods: weight measurements and radioisotopic methods

   Note: Endocrine investigations such as progesterone, oestradiol. E2), luteinising hormone (LH) and follicle stimulating hormone (FSH) levels are considered but not recommended

Treatment

1. Involvement of patients in the decision making process regarding their treatment and provision of appropriate oral and written information
2. Drug treatments
   - Danazol
   - Gestrinone

- Gonadotrophin releasing hormone (GnRH) analogues
- Progestogen releasing intrauterine device (IUD)

3. Surgical treatments
    - Hysteroscopic removal of sub-mucous fibroids or endometrial polyps
    - Endometrial ablation
    - Hysterectomy
    - Prophylactic antibiotics
    - Assessment of risk factors for venous thromboembolism and institution of appropriate prophylactic measures.

    Note: Dilatation and curettage is not therapeutic in cases of heavy menstrual bleeding and is therefore not recommended in the treatment of heavy menstrual bleeding.

MAJOR OUTCOMES CONSIDERED

Diagnosis

- Sensitivity and specificity
- Positive and negative predictive values
- Positive and negative likelihood ratios
- Patient pain and discomfort; patient acceptability

Treatment

- Quality of life and patient satisfaction
- Response to treatment (menstrual blood loss, duration of menstruation, haemoglobin and serum ferritin levels)
- Peri-operative morbidity and mortality
- Post-operative complications and hospital readmission due to complications
- Length of hospital stay and recovery times
- Psychological status and sexual functioning
- Necessity for repeat surgeries
- Long-term effects of hysterectomy
- Therapeutic efficacy
- Cost

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Search Strategy

Individual searches were carried out for each topic of interest. For each subject, the electronic database MEDLINE (CD Ovid version) was searched for the time period January 1966 to February 1998, including foreign language publications.

The searches were performed using relevant medical subject heading (MeSH) terms and relevant textwords. In addition, the electronic database EMBASE was searched between 1974 and 1997 to identify those publications, mainly European, not indexed on MEDLINE. The Cochrane Library was also searched to identify published systematic reviews, meta-analyses and controlled clinical trials kept in their register. Reference lists of non-systematic review articles and studies obtained from the initial search were trawled and recent journals in the Royal College of Obstetricians and Gynaecologists (RCOG) library were handsearched for articles that had not yet been indexed. Experts in the Guideline Development Group were also asked to identify key references. There was no systematic attempt to search the 'grey literature' (conference abstracts, theses, unpublished trials).

Sifting and Reviewing the Literature

Articles were initially retained after reading their title and abstract. The full papers were then obtained and read. Articles not relevant to the subject in question were rejected, as were articles where desired outcomes were not reported.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

For all subject areas, published systematic reviews or meta-analyses were used. If these did not exist, randomised controlled trials were obtained. If there were no randomised controlled trials or randomised controlled trials were not appropriate for a particular clinical question, other appropriate experimental or observational studies were sought.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Identified articles were assessed methodologically and the best evidence was used to form and support the recommendations. If a question could be answered by a good systematic review, meta-analysis, or randomised controlled trial, then studies of weaker design were ignored. The evidence was synthesised using qualitative methods. These involved summarising the content of identified papers into brief statements that accurately reflected the relevant evidence. Meta-analyses, apart from those published, were not performed, due to time constraints and the difficulty of combining studies of various designs.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Informal Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The wording of the recommendations was derived using informal consensus methods.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

The recommendations were graded according to the level of evidence upon which they were based. The grading used was formulated by the Clinical Outcomes Group (COG) and recommended by the National Health Service (NHS) Executive.

Grade A - based on randomised controlled trials
Grade B - based on robust experimental or observational studies
Grade C - based on more limited evidence but the advice relies on expert opinion and has the endorsement of respected authorities

The strength of the evidence is shown after each recommendation. Grade A represents evidence gathered from randomised controlled trials. It is accepted that randomised controlled trials are not the most appropriate study design to investigate diagnostic tests. Therefore, using this grading system means that no recommendations concerning diagnostic tests will be graded A. Grade B represents recommendations based on other robust experimental or observational studies. There may be clinical questions that cannot easily be answered by experimental design but, nevertheless, represent good practice. In such areas with limited experimental evidence, informal consensus was used to derive recommendations. These are Grade C recommendations. The views of the guideline group combined with comments from the extensive peer review, as detailed in the original guideline document, suggest that recommendations with 'C' grading are acceptable to a wide body of expert opinion, pending the results of future research.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not performed.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A copy of the draft guideline and a guideline appraisal document, based on that used by the Scottish Intercollegiate Guidelines Network (SIGN), were sent out to 38 nominated peer reviewers. Twenty-seven people replied, giving a response rate of 71%. The comments made by the peer reviewers and the results from the

guideline appraisal document were taken into consideration by the guideline group before generation of the final guideline. All comments from the peer review were discussed by the guideline group and amendments agreed by informal consensus.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Grades of recommendation (A–C) are defined at the end of the Major Recommendations field.

Indications

1. If a woman continues to complain of heavy menstrual bleeding, despite having used a drug treatment recommended in the first guideline, her menstrual history should be re-evaluated and an abdominal, bimanual and speculum examination performed (C).

Investigations

2. A full blood count should be performed (B).
3. Tests for thyroid function and bleeding disorders should only be performed if there are suggestive features present in the history or on examination (C).
4. No other endocrine investigations are necessary in the investigation of menorrhagia (B).
5. The uterine cavity should initially be investigated using transvaginal ultrasound (B).
6. An endometrial biopsy should be considered for all women with persistent menorrhagia (C).
7. A dilatation and curettage (D&C) does not give additional diagnostic information over and above a hysteroscopy with endometrial biopsy (B).
8. When hysteroscopy is indicated, it allows direct visualization of the uterine cavity and the opportunity for an endometrial biopsy without the need for a general anaesthetic (A).
9. Consideration should be given to performing an objective or semi-objective measurement of menstrual blood loss before deciding upon definitive surgical treatment (C).

Treatment

Patient Issues

10. Patients must be involved in the decision-making process regarding their treatment and be provided with appropriate information to enable them to do this (C).
11. If definitive surgical treatment is intended, the likely outcomes and complications should be discussed with the woman beforehand. These discussions should be backed up with appropriate written information (C).
12. Quality of life issues are important and must be addressed during the collaborative decision making process (C).

Drug Treatments

13. Second line drugs such as danazol, gestrinone, and gonadotrophin releasing hormone analogues are effective in reducing heavy menstrual blood loss but side effects limit their long-term use (A).
14. A progestogen releasing IUD is an effective treatment for reducing heavy menstrual blood loss and should be considered as an alternative to surgical treatment (A).

Surgical Treatments

15. A dilatation and curettage (D&C) is not therapeutic in cases of heavy menstrual bleeding (B).
16. If intrauterine pathology such as sub-mucous fibroids or polyps are found during ultrasonic or hysteroscopic investigation, these should be removed hysteroscopically (B).
17. Endometrial ablative procedures are effective in treating menorrhagia (A).
18. Hysterectomy is an established, effective treatment for menorrhagia (A).
19. The widespread use of hysterectomy as a treatment for menorrhagia should be balanced against its potential mortality and morbidity (C).
20. Prophylactic antibiotics should be given to all women undergoing major surgical treatment for menorrhagia (A).
21. Risk factors for venous thromboembolism should be assessed before hysterectomy and appropriate prophylactic measures instituted (C).

Definitions: Rating Scheme for the Grade of the Recommendation

Grade A: based on randomized controlled trials
Grade B: based on robust experimental or observational studies
Grade C: based on more limited evidence but the advice relies on expert opinion and has the endorsement of respected authorities

CLINICAL ALGORITHM(S)

Algorithms are provided for (1) the management of menorrhagia in secondary care; (2) clinical evaluation of the complaint of menorrhagia; and (3) medical management of the complaint of menorrhagia.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see â œMajor Recommendationsâ).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

The treatment objective in menorrhagia is to alleviate heavy menstrual flow and, consequently, improve quality of life.

There may be cost savings associated with a reduction in unnecessary tests, or with the avoidance of inappropriate surgical intervention. In addition, it is anticipated that there will be health benefits for women with menorrhagia in the form of appropriate investigation, information provision and the opportunity for collaborative decision making, and effective treatment.

Specific benefits of obtaining a full blood count: A full blood count (which includes platelet count) gives extra information about the haematological indices and may reveal an iron deficiency state before anaemia is reached.

Specific benefits of objective or semi-objective measurements of menstrual blood loss:

- The measurement of menstrual blood loss may allow avoidance of further invasive procedures.
- Two studies suggest that the objective measurement of menstrual blood loss may help reassure women who have blood loss measured within normal limits and enable them to decide not to have further treatment.

Specific benefits of involving patients in the decision making process regarding their treatment: Evidence from various areas of healthcare points toward improved patient satisfaction and better medical and surgical outcomes with increased patient participation in the choice of treatment options.

Specific benefits of progestogen releasing intrauterine devices: Progestogen releasing intrauterine devices can offer an alternative to both medical and surgical treatments of menorrhagia. Fertility is preserved and the cost is low compared with surgical options. Less technical skill and training is required for insertion of the LNg20-IUD compared with the training required to undertake hysteroscopic surgery or hysterectomy.

Specific benefits of hysterectomy: The risks of endometrial and cervical cancer are eliminated by total hysterectomy, and an analysis of 12 U.S. case-control studies reported a reduced relative risk of ovarian cancer, ranging from 0.6–0.8.

Subgroups Most Likely to Benefit:

- The majority of women found to have endometrial polyps and sub-mucous fibroids can gain a successful reduction in their menstrual flow by undergoing hysteroscopic removal of these lesions. Hysteroscopic myomectomy or polypectomy are the only surgical procedures for menorrhagia which can be used in women who wish to remain fertile.
- A preliminary study suggests that a progestogen releasing intrauterine device may be beneficial in treating menorrhagia associated with an ultrasound diagnosis of adenomyosis.

POTENTIAL HARMS

- Problems with transvaginal ultrasound are that it is inconclusive and cannot distinguish between polyps and fibroids.
- Endometrial biopsy may miss pedunculated lesions such as submucous fibroids and polyps and may also miss small foci of hyperplasia or carcinoma.
- Dilatation and curettage has small but real risks of morbidity and mortality with the possibility of uterine perforation and cervical laceration. A general anaesthetic, also with attendant risks, is required. In addition, this procedure is inclined to miss focal abnormalities such as polyps and sub-mucous fibroids, which may be the cause of the bleeding.

Side effects of drug treatments

- An average weight gain of 2–4 kg is common with three months of danazol treatment. Other side effects include androgenic effects such as acne, seborrhoea, hirsutism, voice changes, and general complaints including irritability, musculoskeletal pains, and tiredness. Hot flushes and breast atrophy can sometimes result. Most of these side effects are reversible on stopping treatment. However, vocal changes may not always be reversible although this may be related to dose and length of treatment.
- In a study of 23 women treated with goserelin, a gonadotrophin releasing hormone analogue, 91% experienced hot flushes, which is the commonest side effect of this treatment. Treatment with gonadotrophin releasing hormone analogues also results in bone loss.
- Several studies looking at gestrinone in the treatment of endometriosis and the only study that involved gestrinone in the treatment of menorrhagia have described spotting in a majority of the women studied. Other side effects are mainly due to its androgenic action, like danazol, and although mild, are common. Weight gain of 2–3 kg is usual, as is acne and seborrhoea. Hirsutism and muscle cramps may occur. However, these side effects are reversible on cessation of treatment.
- Side effects of a progestrogen releasing intrauterine device included bloating, weight gain, and breast tenderness.

Adverse effects of surgical treatment

- There are still long-term concerns regarding hormone replacement therapy after endometrial ablation or resection. Whilst women who continue to menstruate after surgery are advised to have combined hormone replacement therapy, there is controversy about amenorrhoeic women and whether they should receive combined therapy in case small foci of endometrium still exist or whether it is safe to advocate oestrogen only replacement. Also of concern is how any islands of functional endometrial tissue left behind will behave if they undergo malignant change. The risk is that, because an irregular menstrual pattern or post-menopausal blood loss may not occur, the presentation may be much later and the subsequent prognosis much worse.
- Complications and long-term effects of hysterectomy:
    a. Large population-based studies with analyses stratified by age showed a mortality rate after hysterectomy for non-malignant conditions of one in 2,000 in women under the age of 50.
    b. The Collaborative Review of Sterilization study reported combined major and minor complication rates after hysterectomy for non-malignant conditions of 25% and 43% for vaginal hysterectomy and

abdominal hysterectomy, respectively. Febrile morbidity accounted for the majority of complications. Other studies report major complication rates of 5% and 7% and combined major and minor complication rates of 28% and 46%.

c. Reported complications for hysterectomy procedures include:
    - Haemorrhage
    - Infections (unexplained fever, operative site infection [would infection and pelvic infection] and infection remote from the operative site [mainly urinary tract infection and pneumonia]).
    - Injuries to adjacent organs (mainly the bladder, bowel, and ureter).
    - Thromboembolic disease
    - Wound dehiscence
    - Unintended major surgical procedures (surgical correction of bowel, bladder, and ureter injuries and returns to the operating room in the 8-week post-operative period).
    - Bowel function may be affected. Some studies have reported an increase in constipation.
d. Other long-term effects of hysterectomy include:
    - Endocrine effects (a decline in ovarian function after pre-menopausal hysterectomy with preservation of one or both ovaries)
    - Increased cardiovascular risk in women undergoing hysterectomy with bilateral oophorectomy who did not receive hormone replacement therapy
    - Risk of osteoporosis. Some studies have found significantly reduced bone density in hysterectomised women compared with non-hysterectomised controls even though the ovaries have been conserved.

Subgroups Most Likely to be Harmed:

If pregnancy occurs during treatment with danazol or gestrinone, virilisation of the fetus may occur.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Guidelines are systematically developed statements to assist decisions about appropriate care for specific clinical circumstances. Guidelines are not intended to restrict clinical freedom, but practitioners are expected to use the recommendations as a basis for their practice. Local resources and the circumstances and preferences of individual patients will need to be taken into account. Where possible, recommendations are based on, and explicitly linked to, the evidence that supports them. Areas lacking evidence are highlighted and may form a basis for future research.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Local Protocol Development: It is anticipated that this national guideline will be used as the basis for the development of local protocols which will take into account local service provision and the needs and preferences of the local population. Such local adaptation should take place in a similar multidisciplinary group with collaboration between all interested parties that would be affected by the guidelines. It is essential that commissioners of healthcare, as well as general practitioners and specialists, take part in such a process.

Dissemination and Implementation: The recommendations that form the basis of this national guideline will be widely distributed to relevant and interested parties, including all Fellows and Members of the Royal College of Obstetricians and Gynaecologists (RCOG) and all Directors of Public Health in the United Kingdom (UK). Consideration is being given to making the guideline available via the RCOG website.

A variety of approaches may be necessary to disseminate and implement the local protocols, e.g., distribution of recommendations and algorithms to all specialists and trainees, half-day postgraduate meetings in hospitals, audit sessions and reminders in out-patient clinics. Where possible, patient-specific reminders should be developed locally as this method of implementation has been shown to be effective.

Clinical Audit: The recommendations can be translated into standards for use in the local audit of the management of menorrhagia. The nature of certain recommendations lends themselves particularly to form auditable standards, as the information should be recorded in the case notes and can be easily accessed. A few examples are presented below:

- All women should have either a transvaginal ultrasound or hysteroscopy to investigate their uterine cavity (see "Major Recommendations," recommendation 5).
- All women should have an endometrial biopsy (see â œMajor Recommendationsâ , recommendation 6).
- All women should receive written information about their treatment options (see â œMajor Recommendationsâ , recommendation 10).
- All women having major gynaecological surgery should have antibiotic prophylaxis (see â œMajor Recommendationsâ , recommendation 19).

In addition, the algorithm for â œThe Management of Menorrhagia in Secondary Careâ in conjunction with the Out-Patient Evaluation Form presented in Appendix 2 of the original guideline document could form the basis for local audits.

To enable the impact of this guideline, or any local protocols derived from it, to be audited, hospitals may also wish to record numbers of women referred for menorrhagia to whom the guideline will apply and record the investigations and treatments used.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists. The management of menorrhagia in secondary care. London: RCOG Press; 1999 Jul. 77 p. (Evidence-based clinical guidelines; no. 5). [276 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Jul

GUIDELINE DEVELOPER(S)

Royal College of Obstetricians and Gynaecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

This guideline was developed with funding from the Clinical Effectiveness Programme of the UK Department of Health, National Health Service (NHS) Executive with additional support from the Royal College of Obstetricians and Gynaecologists (RCOG).

GUIDELINE COMMITTEE

- Royal College of Obstetricians and Gynaecologists (RCOG) Guideline Steering Group
- RCOG Guideline Development Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Members of Royal College of Obstetricians and Gynaecologists (RCOG) Guideline Steering Group: Robert Shaw (Chairman); Ian Russell; Ralph Settatree; and Allan Templeton. A representative from the National Health Service (NHS) Executive also participates in this group.

Members of RCOG Menorrhagia Guideline Development Group: RW Shaw, FRCOG (Chairman); I Allen; MA Harper FRCOG; V Hempsall; J Hourahane; MCP Rees MRCOG; SK Smith MRCOG; P Sutton MRCGP.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All the members of the group made formal declarations of interest at the outset which were recorded. These declarations are kept on file at the Royal College of Obstetricians and Gynaecologists (RCOG) and are available on request. The guideline group were of the opinion that the interests declared did not conflict with the guideline process.

GUIDELINE STATUS

This is the current release of the guideline.

The next revision/update is scheduled for 2003

GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available from the Royal College of Obstetricians and Gynaecologists' (RCOG) Bookshop, 27 Sussex Place, Regent's Park, London NW1 4RG; Telephone: +44 020 7772 6276; Fax, +44 020 7772 5991; e-mail: bookshop@rcog.org.uk . A listing and order form are available via the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

A summary of the guideline recommendations is available at the Royal College of Obstetricians and Gynaecologists (RCOG) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on January 8, 2001. It was verified by the guideline developer as of February 6, 2001.

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